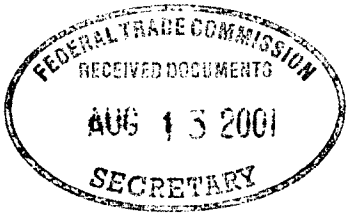
UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION



In the Matter of	
SCHERING-PLOUGH CORPORATION, a corporation,	
UPSHER-SMITH LABORATORIES, INC. a corporation, and	Docket No. 9297
AMERICAN HOME PRODUCTS CORPORATION, a corporation.	The Honorable D. Michael Chappell Administrative Law Judge

MOTION OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO QUASH SUBPOENA SERVED BY UPSHER-SMITH LABORATORIES, INC.

Pursuant to the Federal Trade Commission's Rules of Practice, 16 C.F.R. § 3.34(c), nonparty United States Food and Drug Administration respectfully moves to quash the subpoena duces tecum served on it by Upsher-Smith Laboratories, Inc., in this proceeding. The grounds for this motion are set forth in the accompanying Memoranda.

Dated: August 10, 2001

Respectfully Submitted,

MICHAEL M. LANDA
ACTING CHIEF COUNSEL

By: _____
Carl I. Turner
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AMERICAN HOME PRODUCTS CORPORATION, a corporation.	The Honorable D. Michael Chappell Administrative Law Judge

MOTION OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION TO QUASH SUBPOENA WITH SUPPORTING MEMORANDA

Pursuant to the Federal Trade Commission's ("FTC") Rules of Practice, 16 C.F.R. § 3.34(c), nonparty United States Food and Drug Administration ("FDA") respectfully moves to Quash the subpoena duces tecum served on it by Upsher-Smith Laboratories, Inc., ("Upsher-Smith") on August 1, 2001. The basis for FDA's motion is that Upsher-Smith is required to make a FOI request for any such documents it seeks and, indeed, has already done so. In support of this motion, FDA states as follows.

FACTS

Upsher-Smith seeks "[a] copy of each New Drug Application and Abbreviated New Drug Application submitted after January 1, 1995 on which the 'Chemical/BioChemical/Blood Product Name' is identified as POTASSIUM CHLORIDE. (This subpoena *duces tecum*

seeks the completed Application form (Form 356h or equivalent), but does not seek any attachments or other materials accompanying the Applications." Although counsel for FDA has advised Upsher-Smith of its obligation to seek such records in accordance with the procedures set forth in 21 C.F.R. Part 20, it has declined to withdraw its subpoena.

ARGUMENT

FDA, like most federal agencies, has promulgated regulations under the authority of 5 U.S.C. § 301, which govern the production of records. See also 21 U.S.C. § 371(a). FDA's document disclosure regulations are set forth in 21 C.F.R. Part 20. In particular, 21 C.F.R. § 20.2 provides that an FDA employee who receives a subpoena duces tecum decline to produce the records. As this Commission has recognized, FDA's regulations provide, instead, that FDA treat the subpoena for documents as a request for documents under the Freedom of Information Act. See Order Granting Motions by United States Food and Drug Administration to Quash Subpoenas served by Aventis Pharmaceuticals, Inc. and Andrx Corporation, (FTC No. 9293, Oct. 2, 2000)(finding that "[t]here is no basis for holding that the Commission's Rules of Practice override the FDA's own regulations governing document disclosure.") (citing Metrex Research Corp. v. United States, 151 F.R.D. 122, 124 (D. Col. 1993); Cleary, Gottlieg v. Dep't of Health and Human Services, 844 F.Supp. 770,

787 (D.D.C. 1993); and In Re U.S. Bioscience Sec. Litig., 150 F.R.D. 80, 82 (E.D. Pa. 1993)). Accordingly, the party serving the subpoena is "required to follow the FDA's statutory procedures for requesting documents set forth in 21 C.F.R. Part 20." Id.

Not only is Upsher-Smith aware of the Commission's decision in the Aventis Pharmaceuticals matter and the underlying regulatory provision, it has filed the appropriate FOI request in this action. Notwithstanding its acknowledgment of the proper procedure, however, Upsher-Smith has refused to withdraw its subpoena request. Accordingly FDA moves to quash the referenced subpoena.

Conclusion

FDA respectfully requests that the Federal Trade Commission quash Usher-Smith's subpoena duces tecum.

Respectfully Submitted,

MICHAEL M. LANDA
ACTING CHIEF COUNSEL

By: Carl I. Turner

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CERTIFICATE OF SERVICE

I hereby certify that on August 10, 2001, I caused a copy of the Motion of the United States Food and Drug Administration to Quash Subpoena With Supporting Memoranda to be served by Federal Express, postage prepaid, on:

Donald S. Clark, Secretary
Federal Trade Commission
Room 172
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Hon. D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

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STATEMENT OF CARL I. TURNER PURSUANT TO RULE 3.22(f) OF THE FEDERAL TRADE COMMISSION'S RULES OF PRACTICE

I am an attorney with the Office of Chief Counsel for the United States Food and Drug Administration and submit this statement pursuant to Rule 3.22(f) of the Federal Trade Commission's Rules of Practice, 16 C.F.R. § 3.22(f), in connection with the Motion of the United States Food and Drug Administration To Quash Subpoena With Supporting Memoranda. On August 8, 2001, and August 9, 2001, I spoke with Christopher M. Curran, counsel for Upsher-Smith Laboratories, Inc., in good faith to resolve by agreement the issues raised by FDA's motion to quash. During those conversations, we discussed the requirements of FDA's FOI regulations and this court's order quashing similar subpoenas in Aventis Pharmaceuticals (FTC No. 9293, Oct. 2, 2000); however, with the exception of agreements to limit the request to pending NDA and ANDA applications and that the subpoena service date was August 1, 2001, we were unable to

reach agreement resolving the objections to the subpoena. In addition, we failed to reach agreement that in light of Upsher-Smith filing its FOI request on August 8, 2001, the subpoena should be withdrawn.

Dated: August 10, 2001

Respectfully submitted,

MICHAEL M. LANDA
ACTING CHIEF COUNSEL

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